SEP 13 2012

510(k) SUMMARY

IMPLANET S.A.'S JAZZ SYSTEM

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Implanet S.A.
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Contact Person: Franck Rigal, Director of Quality and Regulatory Affairs

Date Prepared: August 30, 2012

Name of Device and Name/Address of Sponsor

Jazz System

Common or Usual Name

Bone fixation cerclage

Classification Name

888.3010 – Bone Fixation Cerclage

Predicate Devices

Zimmer Spine, Inc.'s Universal Clamp System (K060009, K081622, K091190, K110348).

Intended Use / Indications for Use

The Jazz System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
2. Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis, spondylolisthesis;
3. Spinal degenerative surgery, as an adjunct to spinal fusions.

The Jazz System may also be used in conjunction with other medical implants made of titanium alloy whenever "wiring" may help secure the attachment of other implants.

The JAZZ system is intended to be used with the CALYPSO pedicle screw system.

Technological Characteristics

The device consists of the following components and accessories: polyester (polyethylene-terephthalate) braid; titanium alloy connector and screw; and stainless steel malleable strip and buckle.

Performance Data

In support of this 510(k) Premarket Notification, Implanet S.A. has conducted bench testing to demonstrate that the Jazz System provides adequate mechanical strength for its intended use. The company has conducted these tests based on current version of standards when available and has initiated its own test protocols when necessary to validate certain loading conditions. All bench testing confirmed that the product met the necessary specifications. In addition, the biocompatibility of the device has been confirmed in accordance with ISO-10993, through performance of the following tests:

- Cytotoxicity
- Intracutaneous irritation
- Systemic toxicity (acute, sub-acute, sub-chronic, pyrogenicity)
- Sensitization
- Genotoxicity (bacterial reverse mutation assay, mouse micronucleus test, chromosomal aberration test)
- Implantation

The company has conducted sterilization and shelf life validation in accordance with recognized industry standards.

A list of the tests performed to support substantial equivalence is provided below:

- Static Tensile Test (braid)
- Viscoelastic Characteristics (braid)
- Static Tensile Testing
- Static Axial Compression Corpectomy Construct Testing
- Dynamic Tension Testing
- Dynamic Axial Compression Corpectomy Construct Testing

Substantial Equivalence

The Jazz is very similar to the Zimmer Universal Clamp System. The Jazz has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Jazz and its predicate device raise no new issues of safety or effectiveness. Performance data, including mechanical testing, demonstrate that the Jazz is as safe and effective as the Zimmer Universal Clamp System. Thus, the Jazz is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 13 2012

Implanet S.A.
% Hogan Lovells US, LLP
Ms. Janice Hogan
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K121541
Trade/Device Name: Jazz System
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: Class II
Product Code: JDQ
Dated: September 04, 2012
Received: September 04, 2012

Dear Ms. Hogan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K121541

Device Name: Jazz System

Indications for Use:

The Jazz System is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include the following applications:

1. Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
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The Jazz System is intended to be used with the CALYPSO pedicle screw system.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K121541